UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,806	05/04/2001	Jen Sheen	00786/389002	7904

21559 7590 04/10/2003

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER
COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 04/10/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/848,806	SHEEN, JEN	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) *9 and 17-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 10-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-8 and 10-16, in Paper No. 9 is acknowledged.

Information Disclosure Statement

Applicant's IDS form 1449, filed December 26, 2002, Paper No. 7, was not available to the Examiner at the time of instant Office action. An initialed and dated copy will be mailed to applicant prior to the close of prosecution.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 and 10-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a method of producing a plant having increased resistance to any disease, including disease caused by any pathogen, by regenerating a plant from a non-naturally occurring plant cell that overexpresses a nucleic acid molecule encoding any calcium-dependent protein kinase polypeptide, including any calcium-dependent protein kinase polypeptide designated CDPK2.

The claims do not recite the specific identity of any particular nucleic acid molecule encoding a calcium-dependent protein kinase polypeptide. Absent reference to the particular identity of the nucleic acid molecule a critical element of the claimed invention remains undefined, such that the invention is not adequately described. Furthermore, the specification does not describe the structural and physical features of any nucleic acid molecule encoding a calcium-dependent protein kinase polypeptide that increases disease resistance when overexpressed in a plant. The specification indicates that a plant having increased disease resistance may be produced by overexpressing a calcium-dependent protein kinase polypeptide such as CDPK2 or CDPK4 or polypeptides that consist essentially of the protein kinase domain of a CDPK or CDPKs that are orthologs of *Arabidopsis* CDPKs (page 2 lines 1-21), but such plants are not described. The specification also indicates that SEQ ID NOS: 2 and 4 correspond to CDPK2 and CDPK4 respectively of *Arabidopsis thaliana* (page 11 lines 17-21), but plants that overexpress SEQ ID NOS: 2 and 4 are not described.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lily and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of using them would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No.4/ Friday January 5, 2001/Notices: pp. 1099-1111).

Claims 1-8 and 10-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to a method of producing a plant having increased resistance to any disease, including disease caused by any pathogen, by regenerating a plant from a non-naturally occurring plant cell that overexpresses a nucleic acid molecule encoding any calcium-dependent protein kinase polypeptide, including any calcium-dependent protein kinase polypeptide designated CDPK2.

The specification discloses that expression of a CDPK disclosed in Urao et al. induces the expression of a LUC reporter gene operably linked to several early pathogen defense activated promoters in an *Arabidopsis* protoplast transient expression system (page 13 lines 1-22). However, the specification does not disclose any plant having increased resistance to any disease as a consequence of overexpressing any calcium-dependent protein kinase polypeptide.

Guidance for making and using the claimed invention is necessary for enablement because the ability of nucleic acid molecule encoding a calcium-dependent protein kinase polypeptide to increase disease resistance when expressed in a transgenic plant is unpredictable. The ability of a calcium-dependent protein kinase polypeptide to increase disease resistance would be limited by the cellular environment in which the enzyme is expressed. Enzymatic function would be affected by the amount of enzyme expressed, the availability of substrate, and the presence of absence of other factors that might affect enzyme activity or downstream effects. For example, Lee et al. (Biochemistry, 1998, Vol. 37, pages 6801-6809) teach that calcium-dependent protein kinase polypeptides may differ in their regulatory domains, susceptibility to stimulation by calmodulin, kinetic properties, substrate specificities, and calcium binding properties (page 6801 column 2 first full paragraph; page 6802 column 1 first paragraph; page 6807 column 2 third paragraph through page 6808 column 2 last paragraph). Such differences in biochemical properties among calcium-dependent protein kinase polypeptides could limit their ability to increase disease resistance when expressed in a transgenic plant.

Guidance for making and using the claimed invention is also necessary for enablement because the ability of any nucleic acid molecule encoding any polypeptide to increase disease resistance when expressed in a transgenic plant is unpredictable. The expression of any particular pathogen-induced polypeptide may not be sufficient to increase plant disease resistance because plant disease resistance may require the presence of additional cellular factors. For example, Linthorst et al. teach that constitutive expression of three specific pathogenesis-related proteins (PR-1, GRP and PR-S) did not increase disease resistance in transgenic tobacco plants (The Plant Cell, March 1989, Vol. 1, pages 285-291, see abstract page 285). The requirement for the presence of additional cellular factors to effect plant disease resistance could limit the ability of

any overexpressed nucleic acid molecule and the polypeptide it encodes to increase disease resistance in a transgenic plant.

Given the claim breadth, unpredictability and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify a multitude of non-exemplified calcium-dependent protein kinase polypeptides or the genes encoding them from a multitude of sources, to isolated said genes, and to evaluate the ability of a multitude of non-exemplified genes to increase disease resistance in plants transformed therewith.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5, 8, 10 and 11, and claims 2-4, 6-7 and 12-16 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, and claims 2-8 and 10-16 dependent thereon, is indefinite in the recitation of "disease resistance". It is unclear what types of diseases are encompassed by the claims, as plants are susceptible to a multitude of different diseases.

Claim 1, and claims 2-8 and 10-16 dependent thereon, is indefinite in the recitation of "providing". It is unclear how one would "provide" a non-naturally occurring plant cell suitable for practicing the claimed invention.

Claim 1, and claims 2-5 dependent thereon, is indefinite in the recitation of "non-naturally occurring plant cell". It is unclear how a plant cell, or any living cell or organism, could not be naturally occurring.

Claim 5 is indefinite in the recitation of "plant pathogen". It is unclear what types of pathogens are encompassed by the claims, as plants are susceptible to a multitude of different pathogens.

Claim 8 is indefinite in the recitation of "CDPK2". The meaning of the acronym "CDPK2" is unclear, as an acronym can have more than one meaning, and there is no point of reference for "2".

Claim 10 is indefinite in the recitation of "consists essentially of". It is unclear what would not materially affect the CDPK polypeptide used.

Claim 11 is indefinite in the recitation of "constitutively-active CDPK polypeptide" It is unclear what specific activity would be constitutive.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-8, 11-13 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Lusso et al. (WO 99/02655, published 21 January 1999).

The claims are drawn to a method of producing a plant having increased resistance to any disease, including resistance to any disease caused by plant pathogens, by regenerating any plant from a non-naturally occurring plant cell, including a monocotyledonous or dicotyledonous plant cell and including transgenic plant cells, that overexpress a nucleic acid molecule encoding a

calcium-dependent protein kinase polypeptide (CDPK), including any calcium-dependent protein kinase polypeptide designated CDPK2, wherein the nucleic acid molecule may be an "ortholog" of an *Arabidopsis* gene, and wherein the nucleic acid molecule comprise an inducible promoter.

Lusso et al. teach a method of producing a plant having increased disease resistance, including resistance to disease caused by plant pathogens, by regenerating a plant from a non-naturally occurring plant cell, including a monocotyledonous or dicotyledonous plant cell and transgenic plant cells, that overexpress a nucleic acid molecule encoding a calcium-dependent protein kinase polypeptide (CDPK) under the control of an inducible promoter (page 3 line 16 to page 4 line 29; page 5 lines 5-15; page 7 line 25 to page 8 line 35; pages 21-29, Examples 1-6). While Lusso et al. do not explicitly teach a calcium-dependent protein kinase polypeptide designated "CDPK2", the designation "CDPK2" is not interpreted as limiting "calcium-dependent protein kinase polypeptide", as the designation "CDPK2" is indefinite, as indicated in the rejection under 35 USC 112, second paragraph. The CDPK nucleic acid molecule is inherently an "ortholog" of an *Arabidopsis* gene. The CDPK would be constitutively active in that the expressed enzyme itself does not require further activation.

Claims 1-8 and 10-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Sheen (WO 98/26045, published 18 June 1988).

The claims are drawn to a method of producing a plant having increased disease resistance, including resistance to disease caused by plant pathogens, by regenerating a plant from a non-naturally occurring plant cell, including a monocotyledonous or dicotyledonous cruciferous plant cell and including transgenic plant cells, that ectopically overexpress a nucleic acid molecule encoding a calcium-dependent protein kinase polypeptide (CDPK), including a

CDPK polypeptide that consists essentially of a protein kinase domain or a constitutively active CDPK, and a CDPK derived from *Arabidopsis* or an ortholog thereof, under the control of an inducible, constitutive or tissue-specific promoter.

Sheen teaches a method of producing a plant having increased environmental stress resistance (page 2 line 16 to page 5 line 8; page 23 line 21 to page 35 line 12) by regenerating a plant from a non-naturally occurring plant cell, including a monocotyledonous (page 12, maize for example) or dicotyledonous cruciferous plant cell (page 8 line 23, for example) and including transgenic plant cells, that overexpress a nucleic acid molecule encoding a calcium-dependent protein kinase polypeptide (CDPK), including a CDPK polypeptide that consists essentially of a protein kinase domain (page 3 line 3 for example), and ATCDPK1 or ATCDPK1a (derived from *Arabidopsis*, page 16), under the control of an inducible, constitutive or tissue-specific promoter (page 26 line16 to page 27 line 27). While Sheen does not explicitly teach that the disclosed method increases disease resistance, such an effect would be inherent to the method taught by Sheen, as the claimed method requires only the overexpression of a nucleic acid molecule encoding a calcium-dependent protein kinase polypeptide in a plant, which is taught by Sheen. Furthermore, while Sheen does not explicitly teach the use of a constitutively active CDPK, the CDPK taught by Sheen is presumed to be constitutively active, as the method taught by Sheen does not require an additional step to activate the CDPK, and as a constitutive promoter is used. Sheen also teaches ectopic expression in that Sheen teaches the use of a constitutive promoter (CaMV 35S) for expression, which would necessarily lead to ectopic expression (page 27 lines 15-27). Additionally, while Sheen does not explicitly teach a calcium-dependent protein kinase polypeptide designated "CDPK2", the designation "CDPK2" is not interpreted as limiting

"calcium-dependent protein kinase polypeptide", as the designation "CDPK2" is indefinite, as indicated in the rejection under 35 USC 112, second paragraph.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
April 4, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638